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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/316,624	05/21/1999	SHALOM Z. HIRSCHMAN	4493-19CIP	8051

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EXAMINER
CLOW, LORI A

ART UNIT	PAPER NUMBER
1631	12

DATE MAILED: 02/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/316,624	HIRSCHMAN, SHALOM Z.	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 19, 2000 has been entered.

Response to Arguments

Applicant's arguments filed November 19, 2001 have been fully considered but they are not persuasive. Claims 1-4 remain rejected for the reasons set forth in the previous office action and for the reasons set forth below.

Claims Rejections-35 USC 102

1. Claims 1-4 are rejected under 35 USC 102(e) as being anticipated by Kochel (US 5,849,196). Applicant argues that Product R is a materially different recipe from that of Kochel's. However, the applicants arguments are directed to limitations that are not present in the pending claims, which never specify the exact product make-up of Product R. Furthermore, the specification speaks to only relative amounts of product ingredient and not to exact amounts, leaving open for interpretation what is meant by "about". In such a case, the Reticulose® recipe fits the metes and bounds of the claimed invention.

2. The applicant argues that there are material differences between the two processes. However, it is still not clear that the products resulting from the processes are different, despite the new matter of UV absorbance, not present in the instant application.

3. Applicant argues that "a patentee is free to be his or her own lexicographer" which is acknowledged. However, it is still not stated in the present claims exactly what is Product R.

4. Because the pending claims still include compositions of Kochel within their scope, applicants argument stating the "method claim for treating one disease with one product is not anticipated by a teaching of a method for treating the same disease with a different product" is moot.

5. Applicant argues that Kochel did not intend to treat Rheumatoid Arthritis because of the "ambivalent suggestion that it may be used." However, the fact remains that the the claims in the instant application do not recite particular physical properties of the Product R, nor do they recite particular methods used to isolate and purify Product R of the claims that results in the differing composition. Furthermore applicant is questioning the validity of a US Patent by asking "does Kochel even know what he is talking about?" US Patents have the presumption of validity absent evidence to the contrary.

Kochel (US Patent 5,849,196, filed Oct. 7, 1996) discloses a composition which is derived from the filtration of "Reticulose", which can be used to treat autoimmune disorders, such as rheumatoid arthritis. Kochel discloses the preparation of the composition at columns 5 and 6, and discloses the final proportions of the components. Kochel discloses that the compositions having the lower molecular weight peptides (<8-15 Kd) are useful in the treatment of autoimmune diseases at column 3 lines 1-11. The claims recite Product R, which appears to

be made by specific processes in the specification. The MPEP discusses product-by -process claims in chapter 2100: "Even though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by -process claim is the same as, or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process." See MPEP 2113.

Kochel sets forth products derived from the known product "Reticulose" and methods of using that product, as claimed. The methods Kochel used to produce the composition, as well as the methods of treating rheumatoid arthritis, are very similar to those of the claimed invention. Whether the products resulting from the process are the same, is not clear, and the Office does not have the facilities to perform such comparative analyses. In a discussion of product-by-process claims, the court has said: "[W]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 59 CCPA 1036, 1041, 459 F.2d 531, 535, 173 USPQ 685, 688 (1972). The court further addressed the issue of product-by process claims in In re Best: "the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on 'inherency' under 35 USC 102, on 'prima facie obviousness'

under 35 USC 103, jointly or alternatively, the burden of proof is the same [footnote omitted]." In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977).

Claims Rejections-35 USC 112, second paragraph

6. The rejections made under 35 USC 112, second paragraph are maintained. It is still unclear what is meant by "effective symptom ameliorating amount", even when read in conjunction with the phrase "in a range from about 2.5 microliters to about 40 microliters per kilogram of body weight per day". The fact remains that these ranges simply represent volumes to inject with no mention of concentrations of Product R contained in these volumes.

The metes and bounds of the phrase "effective symptom ameliorating amount" in claims 1 and 4 are unclear. While the claims set forth a volume of solution to be administered, there is no correlation between the volume to be administered, and the active units present in that volume of the formulation, such that one of ordinary skill in the art would be apprised of the scope of the invention. The specification provides two methods for making the Product R, but it is unclear that the two resulting products have the same levels of activity. There is no titration of the active Product R formulations such that one of skill in the art would be able to estimate proper dosages to be given. This is true especially in light of the wide range of volumes to be administered. 2.5 microliters (2.5×10^{-6} liters) is a miniscule amount of liquid, especially in comparison to 1 milliliter (1×10^{-3} liters) of liquid.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and

1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Bill Phillips, whose telephone number is (703) 305-3419, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

MARY K. ZEMAN
PRIMARY EXAMINER
AU1631

February 22, 2002

Lori A. Clow, Ph.D.
Art Unit 1631
Lori A. Clow